

**REMARKS**

Applicant respectfully requests that the foregoing amendments be made prior to examination of the present application. Claim 1 has been amended to include the recitations of claim 24.

**Rejection under 35 USC § 102(b)**

Claims 1, 14, 17, 18, 24, 33, and 34 stand rejected as being anticipated by McClymont et al. (GB 2367493). McClymont et al. discloses a rodent-deterrent composition made from i) a capsicum oleoresin, ii) a polyoxyethylene sorbitan fatty acid ester and iii) a fatty acid triglyceride and iv) water.

The Examiner considers that McClymont's composition is similar to the one of the present invention, because capsicum oleoresin is a vegetable oil that contains capsaicinoids, and fatty acid triglycerides are a vegetable oil. Thus, according to the Examiner, McClymont's composition contains the three components of the composition of the invention.

In contrast, the composition of the present invention contains three different components:

- 1) capsaicinoids combined with:
- 2) a formulation base containing two distinct components, that are
  - a) a vegetable and/or mineral oil, and
  - b) a lipophilic additive.

On the contrary, McClymont's composition contains i) a capsicum oleoresin, ii) a polyoxyethylene sorbitan fatty acid ester and iii) a fatty acid triglyceride which is lipophilic.

However, the polyoxyethylene sorbitan fatty acid ester is not lipophilic, since it is soluble in water. Thus, it can not be considered as a vegetable nor as mineral oil, nor as a lipophilic additive.

Thus, McClymont's composition does not contain a combination of capsaicinoids and a formulation base containing two separate components (oil and lipophilic additive) as in the

present invention. Because McClymont et al. do not disclose all elements of the claimed invention, this reference cannot be anticipatory.

Moreover, in the present invention, the resulting composition is solid or pasty at room temperature. On the contrary, the composition of McClymont et al. is “an oil-in-water emulsion which has moderate phase stability and a large droplet size, giving good overall coverage of treated areas” (page 4, lines 18-20). An oil in water emulsion cannot be solid or pasty without the presence of a surfactant, and the claimed invention does not require the presence of a surfactant. Therefore, the composition of McClymont et al. is not under solid or pasty form, without the presence of a surfactants.

### **Rejection under 35 USC § 103(a)**

The pending claims are rejected as obvious in view of the combination of Mann (US 5,273,754), Mamana (US 2002/0192308), and Hosoya et al. (JP 2001064672). Mann et al. teaches an appetite suppressant composition leading to a decrease in weight, comprising at least i) a heating carminative substance, and ii) a cooling carminative substance. In a preferred embodiment, said heating carminative substance is capsaicin. Mann et al. teaches that the heating carminative substance is “a substance having a gastric heating effect and exhibits a local anaesthetic effect in the stomach (particularly upon the gastric nerves controlling hunger) (column 2, lines 30-33).” However, “an undesirable burning sensation sometimes results upon the ingestion of the heating carminative substance” (column 3, lines 31-33).

Surprisingly, the present invention discovered that the incorporation of a formulation base containing both a vegetable and/or mineral oil and a lipophilic additive, which is solid or pasty at room temperature, results in a composition which lacks any irritant effect on the gastric mucosa (see the in vivo test on page 11).

Mann et al. does not teach to add any formulation base containing a vegetable oil and/or mineral oil and a lipophilic additive which is solid or pasty at room temperature as in the invention, since it only discloses adding either “cooling carminative substances” (e.g. peppermint, menthol, spearmint, carvone or mixture thereof), amino acid (e.g. L-methionine, D-phenylalanine, glycine and mixtures thereof), and/or anxiolytic substance (e.g. valerian,

damiana, chamomile, kava, passion flower, hops, skullcap, St John's Wort, extracts thereof or mixtures thereof).

Furthermore, neither Mamana et al., nor Hosaya et al., which disclose respectively an appetite suppressant composition and a weight reducing composition, teach to counteract the gastric burning effect of the capsaicinoids by the use of formulation base containing a vegetable oil and/or mineral oil and a lipophilic additive.

Finally, none of these documents teach the use of lipophilic additive which is solid or pasty at room temperature in their composition.

Accordingly, it would have not been obvious for one of ordinary skill in the art to associate a formulation base containing a vegetable oil and/or mineral oil and a lipophilic additive with capsaicinoids in order to attenuate its gastric burning effect. Therefore, the composition according to the invention is not obvious, and the rejection should be withdrawn.

#### **Conclusion**

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.


The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect

information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By 

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